PSJ3

Exhibit 80A

For Internal Use Only – Not for Distribution

What's Inside . . .

Below is a list of the contents of this binder, the source of this information, as well as its recommended use. **Please note, some items are for your use only and are not to be distributed outside the company. Please use your discretion among the documents that are available for external use. Your job is to help answer their specific questions, not to give physicians a huge stack of information that they may or may not have an interest in. Not every physician will want or need every document.**

Item Name	Source and Date	Suggested Use	For External Distribution?
OxyContin Talking Points	Developed and approved by Abbott on July 7, 2001	For your information. This document presents the approved messages that we want to communicate about OxyContin.	No
Some Answers Regarding OxyContin	Developed and approved by Abbott on September 17, 2001	For your information. This document provides a guide as to how to answer some of your customers' specific questions.	No
Pain Management Standards	Joint Commission on the Accreditation of Healthcare Organizations Effective January 1, 2001	This document can be distributed in response to questions related to the need for pain medications like OxyContin and whether hospital-based physicians should consider prescribing it for their patients.	Yes
Pain Management Guidelines	Federation of State Medical Boards Adopted May 2, 1998	This document can be distributed in response to questions related to the need for pain medications like OxyContin and whether hospital-based physicians should consider prescribing it for their patients. Specifically, you may want to distribute this document in response to questions relating to legal matters.	Yes
OxyContin White Paper	Purdue Pharma July 27, 2001	This document can be distributed in response to requests for more information about OxyContin. You also may want to distribute it in response to questions about OxyContin-related deaths or legal matters.	Yes

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Item Name	Source and Date	Suggested Use	For External Distribution?
OxyContin Package Insert	Purdue Pharma July 2001	The package insert is the standing reference for health care professionals for information on prescription medications. It includes the FDA-approved indication for use, data from clinical trials, adverse effects and warnings.	Yes
Letter to Healthcare Professionals	Purdue Pharma July 18, 2001	This document can be distributed in response to requests for more information about OxyContin.	Yes
Box Warning Talk Paper	U.S. Food and Drug Administration July 25, 2001	For your information. This document describes the most recent box warning label and FDA guidance on OxyContin.	No
News Articles	Several news articles discussing issues relating to OxyContin	These articles provide additional background, and can be provided in response to requests for more information.	Yes

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OxyContin
Abbott Talking Points

OxyContin is a valuable breakthrough medical advance providing great relief for patients suffering from moderate to severe pain, and is safe and effective when used properly.

- OxyContin is a highly effective treatment that helps millions of people suffering from moderate to severe pain, such as patients experiencing post-operative pain.
- For many patients who may not have another pain relief option, OxyContin can increase the patient's quality of life and help them lead more active and productive lives.

Abbott works with hospitals and hospital-based physicians who may wish to prescribe OxyContin to help patients control moderate to severe pain.

- Abbott is responsible only for certain hospital segments and hospital-based specialists whose patients can benefit greatly from OxyContin's benefits – such as orthopedic surgeons, neurosurgeons, and anesthesiologists.
- Anesthesiologists, who specialize in pain management, write more than half of Abbott-related OxyContin prescriptions.
- Abbott has a limited role with respect to OxyContin. Purdue manufactures OxyContin, is responsible for the product's marketing and distribution and has its own sales force to market OxyContin to non-hospital based physicians.
- Abbott does not distribute OxyContin to pharmacies or elsewhere.

Abbott is concerned about abuse and diversion of OxyContin, and supports effective action to assure that it is only available to those with medically diagnosed needs.

- It is vital that OxyContin be available to people who need this therapy and could potentially lead more productive lives because of the medical relief that OxyContin offers. It is equally important that OxyContin be kept out of the hands of people who are misusing it.
- We support education and other measures to assure only proper control and use of OxyContin and other opioids.
- We support Purdue Pharma in its efforts to work proactively with the medical community and law enforcement officials on ways to protect the public while assuring availability of OxyContin to those with medical needs.
- Partnering with Purdue, we have provided education to hospitals and hospital-based physicians to help them use OxyContin properly and prevent abuse or diversion.
- We have acted responsibly and will continue to do so to help patients and protect the public.

Distributed October 2001

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Responsive only, when asked about lawsuits

While we understand concerns about the abuse of OxyContin, these lawsuits cloud the issue and divert attention from effective solutions.

- The real focus should be on the benefits of this breakthrough drug and ways to ensure its availability while preventing abuse and diversion.

Distributed October 2001

Answers Regarding OxyContin

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Some Answers Regarding OxyContin

This document provides answers to some of the common questions you have raised about OxyContin. We've organized this document into two sections, one with answers to questions you may be receiving from physicians, and one with answers to some of your own questions.

This document is for your use only and should not be distributed to individuals outside the company.

Physician questions:

Q1. ***Is OxyContin safe to prescribe to my patients?***

- Yes. OxyContin is safe to prescribe to your patients for moderate to severe pain consistent with its approved indications and product labeling.
- OxyContin was approved by the FDA in 1995.
- OxyContin is a breakthrough medical advance providing great relief for patients suffering from moderate to severe pain, such as postoperative pain and pain from malignant and non-malignant sources. It is safe and effective when used properly. However, it may not be the right pain medication for all of your patients.
- For appropriate patients, OxyContin can increase their quality of life and help them lead more active and productive lives.
- The Joint Commission on the Accreditation of Healthcare Organizations recognizes the importance of treating a patient's pain. JCAHO now requires accredited hospitals to implement new standards that make pain management a required part of all treatment plans. I have a copy of these standards and the current product labeling for your information.

Q2. ***I sometimes prescribe OxyContin and I am concerned about possible legal action; can I see copies of your call cards?***

- OxyContin is safe and effective for moderate to severe pain when used properly and prescribed only to people with medically diagnosed needs consistent with OxyContin's indications and product labeling.
- Call cards are just our way of keeping track of the physicians we visit. They are a tool for internal record keeping at Abbott.
- It is Abbott's corporate policy not to distribute its general internal business records, including these notes, because of business confidentiality.
- If you have legal questions, you may want to try contacting the AMA or one of the pain management associations. Several of these groups have resources for physicians concerned about legal action.

October 2001

- I think it's also important for you to know that the DEA has strongly supported the establishment of "Model Guidelines for the Use of Controlled Substances in Pain Management." This document was developed by the Federation of State Medical Boards and reflects currently accepted standards that may be used by medical professionals and regulators. Purdue Pharma also published a white paper on Proper Use vs. Criminal Abuse of OxyContin. If you are not familiar with these documents, I have copies I can leave with you.

Q3. Can you tell me anything about deaths that I've heard were connected to OxyContin?

- Abbott does not have specific information on these cases and we don't want to speculate about the causes of these deaths.
- Abbott has a limited role with respect to OxyContin. Abbott works with hospitals and hospital-based physicians who may wish to prescribe OxyContin for patients with a medically diagnosed need for the drug. For example, anesthesiologists write more than half of our OxyContin prescriptions.
- Purdue manufactures OxyContin and is responsible for its marketing and distribution. Purdue, therefore, gathers information on deaths attributed to their product and reports that information to the FDA.
- According to Purdue's Web site, in over 90 percent of the cases they have examined, deaths among abusers are caused by the use of multiple drugs, usually including alcohol. Purdue also says it has engaged third parties to evaluate the data provided by coroners and state medical examiners to determine more accurately how many deaths can correctly be attributed to OxyContin abuse.

Q4. I'm concerned that pharmacies may be unable to fill prescriptions for OxyContin. What is Abbott doing to ensure patient access to it?

- We share your concern about access to OxyContin. Its continued availability is very important for patients suffering from moderate to severe pain.
- Abbott supports effective action to assure that it is available only to those with medically diagnosed needs consistent with OxyContin's indications and product labeling.
- Abbott, however, does not distribute OxyContin to pharmacies or elsewhere. We work with hospitals and hospital-based physicians who may wish to prescribe OxyContin to help patients control moderate to severe pain.
- We've learned from Purdue that it is working extensively with pharmacists to provide them information about diversion and how to deal with it. Purdue has sent a mailing on anti-diversion tactics to over 60,000 pharmacists, is faxing information to pharmacists on how to spot diverters, has provided a grant for pharmacists who help identify and prosecute drug diverters, and has a national pharmacy speaker program. The sales representatives are making 2-3 pharmacy calls per day and distributing "Do Not Crush" stickers for OxyContin prescription bottles.

Q5. How widespread is addiction to OxyContin? What does the data show about addiction trends and locations? What about other opioid-based pain medications?

- We do not believe that OxyContin is more addictive than other opioid analgesics.
- The National Institute on Drug Abuse has said that most patients using opioids for pain do not become addicted, and the Center for Substance Abuse Treatment, through their Advisory publication, has voiced a similar view. Even data from the U. S. Government's Drug Abuse Warning Network shows that in 2000, oxycodone in all forms was mentioned in only 1.8 percent of prescription medication related Emergency Room visits, ranking 15th on the list of drugs for abuse and well behind medications such as acetaminophen, hydrocodone, and aspirin. [Source: Drug Abuse Warning Network, Detailed Emergency Department Tables, Table 2.06a, August 17, 2001]

Q6. What is Abbott doing about OxyContin abuse?

- Abbott is concerned about abuse and diversion of OxyContin and supports effective action to assure that it is only available to those with medically diagnosed needs.
- As OxyContin's manufacturer and distributor, Purdue Pharma is working proactively with the medical community and law enforcement officials on ways to protect the public while assuring availability of OxyContin to those with medical needs. As a co-promoter of OxyContin, Abbott supports Purdue Pharma in these efforts.
- Partnering with Purdue, we have provided education to hospitals and hospital-based physicians to help them use OxyContin properly and prevent abuse or diversion. We have acted responsibly and will continue to do so to help patients and protect the public.

Q7. Now that a box warning has been added to the product insert, am I protected against legal actions?

- The new product labeling does not change the safety, efficacy or indications for OxyContin in any way. OxyContin is safe and effective when used properly and prescribed only to people with medically diagnosed needs consistent with OxyContin's indications and product labeling.
- The FDA continues to recommend that physicians provide appropriate pain control for patients who are living with moderate to severe pain, while also recognizing the potential problem for abuse of all opioids.
- The labeling changes highlight information that was previously in the package insert and makes certain that this information is more readily accessible.
- If you are prescribing the drug according to the appropriate indications and product labeling, you shouldn't be concerned.
- If you have additional questions, you may want to contact the specialty medical society you may belong to. Several of these organizations have resources for

physicians concerned about legal action. I'm also happy to share a copy of some pain management guidelines developed by the Federation of State Medical Boards and the FDA press release regarding the new warning.

Q8. What can you tell me about the doctor who was indicted in Florida?

- Court records in this case are limited, and we do not have significant information beyond what has appeared in the news media. It would be inappropriate for anyone to speculate about this case.
- From news accounts, it appears that this physician was charged with 80 counts of drug trafficking and related charges, connected to a very high volume of prescriptions for opioids. He and a member of his office staff had been previously charged with Medicare fraud.
- It is appropriate for responsible physicians to prescribe OxyContin to your patients for moderate to severe pain consistent with its approved indications and product labeling.

Q9. What about the problem of overly aggressive patients?

- Abbott promotes this pain medication only to hospitals and hospital-based physicians. Our customers are dominantly specialists in areas who have experience and expertise in pain management issues, as well as the kinds of patients who may need such medications.
- We have not had significant reports of such problematic behavior in such settings.
- Doctors may want to seek information or guidance from medical associations with which they are affiliated.

Sales-force questions:

Q10. What is Abbott's response to the recent FDA "Talk Paper"?

- Abbott believes, as does the FDA, that OxyContin is safe and effective when used properly.
- Abbott supports effective action to assure only proper control and use of OxyContin and other opioids.

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Q11. ***I heard that a Purdue sales representative is named in a class action suit and I'm concerned about possible legal repercussions against us. What is Abbott doing to ensure that this doesn't happen to us?***

- We do realize this issue is of concern to our sales force. If you are representing the product in the manner in which you were trained, you should not worry about legal action. Abbott will provide all necessary support to any employee who works in accordance with proper procedures.

Q12. ***What should I do if I am contacted by an attorney or the media regarding OxyContin?***

- It is the Hospital Products Division's policy for all media inquiries to be directed to the public affairs department: Stacey (Tischler) Eisen at 847/935-2828 or Tareta Lewis at 847/938-4310.
- If an attorney contacts you, advise that attorney that he/she must contact Abbott's legal department directly. Then, please contact your district manager, who will relay the information to the appropriate Abbott attorney.

Q13. ***What is Abbott's position on the lawsuits that have been filed about OxyContin?***

- While we understand concerns about the abuse of OxyContin, these lawsuits cloud the issue and divert attention from effective solutions.
- The real focus should be on the benefits of this breakthrough drug and ways to ensure its availability while preventing abuse and diversion.

Q14. ***What can I do to help ensure the continued availability of this product for people who need it?***

- Please continue to let us know what questions you receive from physicians and what assistance we can provide you in educating physicians about the proper use of OxyContin.

Pain Management

Joint Commission on Accreditation of Healthcare Organizations
Pain Standards for 2001

Right and Ethics Functional Chapter

Assessment of Patients Functional Chapter
Care of Patients Functional Chapter

Education of Patients Functional Chapter

Continuum of Functional Chapter
Improving Organization Performance Functional Chapter

There are eleven chapters of functions or activities required of accredited health care organizations. These functional chapters contain standards which are found in the various accreditation standards manuals published by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Manuals address health care organizations providing ambulatory care, behavioral health care, home care, hospice, hospital, and long term care.

The new "pain" standards and some examples are "pulled out" of the six chapters in which they appear in these six Manuals and are shown below for your information. These new standards are effective for surveys conducted after January 1, 2001. **Both the Standard and its Intent are scored during on-site surveys of an organization's performance.**

However, please note: the Examples of Implementation provided are **NOT** standards nor are they required ways to meet a standard. They are only examples of how other organizations have successfully demonstrated compliance with a standard.

Right and Ethics Functional Chapter

Standard
RI.1.2.7
The health care organization addresses care at the end of life.

Intent of RI.1.2.7
Dying patients have unique needs for respectful, responsive care. All staff are sensitized to the needs of patients at the end of life. Concern for the patient's comfort and dignity should guide all aspects of care during the final stages of life.

The health care organization's framework for addressing issues related to care at the end of life provide for

- providing appropriate treatment for any primary and secondary symptoms, according to the wishes of the patient or the surrogate decision maker;
- managing pain aggressively and effectively;
- sensitively addressing issues such as autopsy and organ donation;
- respecting the patient's values, religion, and philosophy;
- involving the patient and, where appropriate, the family in every aspect of care; and
- responding to the psychological, social, emotional, spiritual, and cultural concerns of the patient and the family.

Effective pain management is appropriate for all patients, not just for dying patients (see standards RI.1.2.8 and PE.1.4).

Standard
RI.1.2.8
Patients have the right to appropriate assessment and management of pain.

Intent of RI.1.2.8
Pain can be a common part of the patient experience; unrelieved pain has adverse physical and psychological effects. The patient's right to pain management is respected and supported. The health care organization plans, supports, and coordinates activities and resources to assure the pain of all patients is recognized and addressed appropriately. This includes:

- Initial assessment and regular re_assessment of pain;
- Education of all relevant providers in pain assessment and management;
- Education of patients, and families when appropriate, regarding their roles in managing pain as well as the potential limitations and side effects of pain treatments; and
- After taking into account personal, cultural, spiritual, and/or ethnic beliefs, communicating to patients and families that pain management is an important part of care.

Assessment of Patients Functional Chapter

Standard
PE.1.4
Pain is assessed in all patients.

Intent of PE.1.4
In the initial assessment, the organization identifies patients with pain. When pain is identified, the patient can be treated within the organization or referred for treatment. The scope of treatment is based on the care setting and services provided. A more comprehensive assessment is performed when warranted by the patient's condition. This assessment and a measure of pain intensity and quality (eg, pain character, frequency, location, and duration), appropriate to the patient's age, are recorded in a way that facilitates regular reassessment and follow-up according to criteria developed by the organization.

Examples of Implementation for PE.1.4

1. All patients at admission are asked the following screening or general question about the presence of pain: Do you have pain now? Have you had pain in the last several months? If the patient responds "yes" to either question, additional assessment data are obtained:

    a. pain intensity (use a pain intensity rating scale appropriate for the patient population; pain intensity is obtained for pain at present, at worst, and at best or least; if at all possible, the pain rating scale is consistently used in the organization and between disciplines)

    b. location (ask the patient to mark on a diagram or point to the site of pain)

    c. quality, patterns of radiation, if any, character (elicit and record the patient's own words whenever possible)

    d. onset, duration, variations and patterns

    e. alleviating and aggravating factors

    f. present pain management regimen and effectiveness

    g. pain management history (including a medication history, presence of common barriers to reporting pain and using analgesics, past interventions and response, manner of expressing pain)

h. effects of pain (impact on daily life, function, sleep, appetite, relationships with others, emotions, concentration, etc.)

i. the patient/client's pain goal (including pain intensity and goals related to function, activities, quality of life)

j. physical exam/observation of the site of pain

2. Patient/clients often have more than one site of pain. An assessment system or tools with space to record data on each site is provided on the assessment sheet.

3. A hospital may need to use more than one pain intensity measure, depending on their patient/client population. For example, a hospital serving both children and adults selects a scale to be used with each of those patient populations. Assessment of cognitively impaired patients may also require assessment of behavioral factors signaling pain or discomfort.

4. Staff are educated about pain assessment and treatment including the barriers to reporting pain and using analgesics. Staff encourage the reporting of pain when a patient/client and/or family member demonstrates reluctance to discuss pain, denies pain when pain is likely to be present (for example, post-operative, trauma, burns, cardiac emergencies), or does not follow through with prescribed treatments.

5. Pain intensity scales are enlarged and displayed in all areas where assessments are conducted. For organizations using clinical pathways, pain assessment is incorporated in some way, into every appropriate clinical pathway.

An organization selects pain intensity measures to insure consistency across departments; for example, the 0-10 scale, Wong Baker FACES Pain Rating Scale (smile-frown), and the Verbal descriptor scale. Adult patients/clients are encouraged to use the 0-10 scale. If they cannot understand or are unwilling to use it, the smile-frown or the verbal scale is used.

A unit caring for persons with Alzheimer's disease developed a pain scale for each resident based on their long-standing knowledge of their residents and their knowledge of the common pain syndromes in elderly persons.

A pediatric hospital includes, in its introductory information for parents, information about pain and pain assessment, including parents' role in interpreting behavioral changes of their child that may indicate pain or discomfort.

Care of Patients Functional Chapter
Overview

The goal of the care of patients function(1) is to provide individualized care in settings responsive to specific patient needs.

Patients deserve care that respects their choices, supports their participation in the care provided, and recognizes their right to experience achievement of their personal health goals. The goals of patient care are met when the following processes are performed well:

- Providing supportive care;
- Treating of a disease or condition;
- Treating symptoms that might be associated with a disease, condition, or treatment (eg, pain, nausea, or dyspnea);
- Rehabilitating physical or psychosocial impairment; and
- Promoting health.
- The standards in this chapter address activities involved in these processes, including
- planning care;
- providing care;
- monitoring and determining the outcomes of care;
- modifying care; and
- coordinating follow-up.

These activities may be carried out by medical, nursing, pharmacy, dietetic, rehabilitation, and other types of providers. Each provider's role and responsibility are determined by their professional skills, competence, and credentials; the care or rehabilitation being provided; health care organization policies; and relevant licensure, certification, regulation, privileges, scope of practice, or job description.

Standard
TX.3.3
Policies and procedures support safe medication prescription or ordering.

Intent of TX.3.3

Procedures supporting safe medication prescription or ordering address;

- distribution and administration of controlled medications, including adequate documentation and record keeping required by law;
- proper storage, distribution, and control of investigational medications and those in clinical trial;
- situations in which all or some of a patient's medication orders must be permanently or temporarily canceled, and mechanisms for reinstating them;
- "as needed" (PRN) and scheduled prescriptions or orders and times of dose administration;
- appropriate use of patient controlled analgesia (PCA), spinal/epidural or intravenous administration of medications, and other pain management techniques utilized in the care of patients with pain;
- control of sample drugs;
- distribution of medications to patients at discharge;
- procurement, storage, control, and distribution of prepackaged medications obtained from outside sources;
- procurement, storage, control, distribution, and administration of radioactive medications;
- procurement, storage, control, distribution, administration, and monitoring of all
  •blood derivatives(2) and
  •radiographic contrast media.

Examples of Evidence of Performance for TX.3.3

1. Before initiating patient-controlled analgesia (PCA) for surgical patients, an interdisciplinary team of physicians, pharmacists and nurses reviewed the literature on PCA, drafted policies, procedures, and standing orders, obtained approval from the pharmacy and therapeutics committee and medical staff, oriented all staff, and conducted a pilot test on the general surgery patient care unit.

Standard
TX.5.4
The patient is monitored during the post-procedure period.

Intent of TX.5.4
The patient is monitored continuously during the post-procedure period. The following items are monitored:

a. Physiological and mental status;

b. Status of or findings related to pathological conditions, such as drainage from incisions;

c. Intravenous fluids and drugs administered, including blood and blood components;

d. Impairments and functional status;

e. **Pain intensity and quality (eg, the character, frequency, location, and duration of pain), and responses to treatments; and**

f. Unusual events or postoperative complications and their management.
Results of monitoring trigger key decisions, such as transfer to an alternative level of care due to a precipitous change in vital signs, or discharge.

Standards, Intents, and Examples for Rehabilitation Care and Services(3)

Rehabilitation is designed to achieve an optimal level of functioning, self-care, self-responsibility, independence, and quality of life. Achieving the patient's optimal level of function means restoring, improving, or maintaining the patient's assessed level of functioning. Rehabilitation services aim to minimize symptoms, exacerbation of chronic illnesses, impairments, and disabilities.
Qualified professionals provide rehabilitation services consistent with professional standards of practice. All interventions encourage the patient to make choices, to sustain a sense of achievement about treatment progress, and if necessary, to modify participation in the rehabilitation process.
Assessment (4) identifies the patient's physical, cognitive, behavioral, communicative, emotional, and social status and identifies facilitating factors that may influence attainment of rehabilitation goals. Problems may include;

- substance use disorders;
- emotional, behavioral, and mental disorders;

- cognitive disorders;
- communicative disorders;
- developmental disabilities;
- vision and hearing impairments and disabilities;
- physical impairments and disabilities; and
- **pain interfering with optimal level of function or participation in rehabilitation.**

Assessment also helps identify services and accommodations helpful to increasing the patient's readiness for rehabilitation.

The rehabilitation plan identifies goals and services and interventions to meet them. Rehabilitation provides patients with skills and supports to function in an environment with as much independence and choice and as little supervision and restrictiveness as possible. Decisions are based on regular reassessment and reliable measures of patient needs, strengths, symptoms, behavioral patterns, and goal achievement. The patient and clinician agree on care choices

Rehabilitation provides access to community resources and services that promote continued goal achievement and independence after rehabilitation concludes.

Education of Patients Functional Chapter

Standard
PF.3.4
Patients are educated about pain and managing pain as part of treatment, as appropriate.

Intent of PF.3.4
When appropriate, patients and families are instructed about understanding pain, the risk for pain, the importance of effective pain management, the pain assessment process, and methods for pain management, when identified as part of treatment.

Examples of Evidence of Performance for PF.3.4

- Examples of patient and family educational materials
- Organization-wide policies and procedures defining responsibilities for patient or family
- Progress notes

- Flowcharts
- Referral and consultation notes
- Interviews with clinical staff

Continuum of Care Functional Chapter

Standard
CC.6.1
The discharge process provides for continuing care based upon the patient's assessed needs at the time of discharge.

Intent of CC.6.1
Discharge planning focuses on meeting patients' health care needs after discharge. Discharge planning identifies patients' continuing physical, emotional, symptom management (eg, pain, nausea, or dyspnea), housekeeping, transportation, social, and other needs, and arranges for services to meet them.
Discharge services may include;

- adult foster care;
- case management;
- home health services;
- hospice;
- long-term care facilities;
- ambulatory care;
- support groups;
- rehabilitation services; and
- community mental health.

Discharge planning involves the patient, the family, the practitioner primarily responsible for the patient, nursing and social work professionals, and other appropriate staff. Staff members help the patient and family adapt to the plan of care.

Improving Organization Performance Functional Chapter

Standard
PI.3.1
The organization collects data to monitor its performance.

Intent for PI.3.1
Performance monitoring and improvement are data driven. The stability of important processes can provide the organization with information about its performance. Every organization must choose which processes and outcomes (and thus which types of data) are important to monitor based on its mission and the scope of care and services it provides. The leaders prioritize data collection based on the organization's mission, care and services provided, and populations served (see LD.4.2 for priority setting). Data that the organization considers for collection to monitor performance include the following:

- Performance measures related to accreditation and other requirements;
- Risk management;
- Utilization management;
- Quality control;
- Staff opinions and needs;
- Behavior management (5) procedures, if used;
- Outcomes of processes or services;
- Autopsy results, when performed;
- Performance measures from acceptable databases;
- Customer demographics and diagnoses;
- Financial data;
- Infection control surveillance and reporting;
- Research data;
- Performance data identified in various chapters of this manual; and the appropriateness and effectiveness of pain management.

Organizations are required to collect data about the needs, expectations, and satisfaction of individuals and organizations served. Individuals served and their family members can provide information that will give an

organization insight about process design and functioning. The organization asks them about;

- their specific needs and expectations;
- their perceptions (6) of how well the organization meets these needs and expectations; and
- how the organization can improve.

The organization can use a number of ways to get input from these groups, including satisfaction surveys, regularly scheduled meetings held with these groups, and focus groups.

One Final Note: If the health care organization does not know how well it is managing pain, leaders should be sure that questions relating to pain assessment and management are included on the tool used to collect data about how well the organization is meeting the specific needs and expectations of the individuals served by that organization.

Notes

1. function A goal-directed, interrelated series of processes, such as continuum of care or management of information.
2. blood derivative A pooled blood product, such as albumin, gamma globulin, or Rh immune globulin, whose use is considered significantly lower in risk than that of blood or blood components.
3. Effective January 1, 2000.
4. Described in the "Assessment of Patients" chapter of this manual.
5. The use of basic learning techniques, such as biofeedback, reinforcement, or aversion therapy, to manage and improve an individual's behavior.
6. To better measure the performance of organizations on how well they meet the needs, expectations and concerns of individuals, the Joint Commission is moving from the term satisfaction toward the more inclusive term perception of care and service. By using this term, the organization will be prompted to assess not only individuals' and/or families' satisfaction with care or treatment, but also whether their needs and expectations are met by the organization.

Pain Management Guidelines

Prepared for internet access by the
University of Wisconsin Pain & Policy Studies Group

MODEL GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN

THE FEDERATION OF STATE MEDICAL BOARDS OF THE UNITED STATES, INC.

(Adopted May 2, 1998)

Section I: Preamble

The (*name of board*) recognizes that principles of quality medical practice dictate that the people of the State of (*name of state*) have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as to reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. Physicians are referred to the U.S. Agency for Health Care and Research Clinical Practice Guidelines for a sound approach to the management of acute[1] and cancer-related pain.[2]

The medical management of pain should be based upon current knowledge and research and includes the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

The (*state medical board*) is obligated under the laws of the State of (*name of state*) to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing, dispensing, or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider prescribing, ordering, administering, or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.

Each case of prescribing for pain will be evaluated on an individual basis. The board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs including any improvement in functioning, and recognizing that some types of pain cannot be completely relieved.

The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

Section II: Guidelines

The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control:

1. Evaluation of the Patient

A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record should also document the presence of one or more recognized medical indications for the use of a controlled substance.

2. Treatment Plan

The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

3. Informed Consent and Agreement for Treatment

The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one

physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities including (1) urine/serum medication levels screening when requested (2) number and frequency of all prescription refills and (3) reasons for which drug therapy may be discontinued (i.e. violation of agreement).

4. Periodic Review
At reasonable intervals based upon the individual circumstance of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives such as improvement in patient's pain intensity and improved physical and/or psychosocial function, such as ability to work, need of health care resources, activities of daily living, and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the physician should re-evaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

5. Consultation
The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

6. Medical Records
The physician should keep accurate and complete records to include (1) the medical history and physical examination (2) diagnostic, therapeutic and laboratory results (3) evaluations and consultations (4) treatment objectives (5) discussion of risks and benefits (6) treatments (7) medications [including date, type, dosage, and quantity prescribed] (8) instructions and agreements and (9) periodic reviews. Records should remain current and be maintained in an accessible manner and readily available for review.

7. Compliance with Controlled Substances Laws and Regulations
To prescribe, dispense, or administer controlled substances, the physician must be licensed in the state, and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (*any relevant documents issued by the state medical board*) for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions
For the purposes of these guidelines, the following terms are defined as follows:

Acute pain: Acute pain is the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma and

acute illness. It is generally time limited and is responsive to opioid therapy, among other therapies.

Addiction: Addiction is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

Analgesic Tolerance: Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Chronic Pain: A pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

Pain: an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence: Physical dependence on a controlled substance is a physiologic state of neuroadaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction: Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

Substance Abuse: Substance abuse is the use of any substance(s) for non-therapeutic purposes; or use of medication for purposes other than those for which it is prescribed.

Tolerance: Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose.

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[1]Acute Pain Management Guideline Panel. Acute Pain Management: Operative or Medical Procedures and Trauma. Clinical Practice Guideline. AHCPR Publication No. 92-0032. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. February 1992.

[2]Jacox A, Carr DB, Payne R, et al. Management of Cancer Pain. Clinical Practice Guideline No. 9. AHCPR Publication No. 94-0592. Rockville, Md. Agency for Health Care Policy and Research, U.S. Department of Health and Human Resources, Public Health Service. March 1994.

White Paper

PURDUE

For Immediate Release

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OxyContin® Tablets: Proper Use Vs. Criminal Abuse
The Role of OxyContin Tablets in Pain Treatment

Pain is a thief. It steals people's jobs, their relationships, their happiness — indeed, the very quality of their lives. Pain affects our productivity, our pocketbooks, and our peace of mind. In America alone, the American Pain Foundation estimates that there are 50 million people living with chronic pain — and they don't need to. Therapies exist today that can provide most of those people with effective pain relief. Yet tens of millions remain untreated or under-treated.

For the past 15 years, Purdue Pharma L.P. has taken the lead in pain management. We develop and market opioid analgesics for the treatment of moderate to severe pain, and we devote extensive resources to educate the healthcare community about their appropriate use. Our efforts and those of several advocacy organizations to free patients from unneeded pain have begun to bear fruit. The Veterans Administration Hospital System, the largest single healthcare system in the world, now recognizes pain as the **The Fifth Vital Sign™** [1]. This means that every time patients are visited by a doctor or nurse, their pain is charted along with their temperature, pulse, respiration rate, and blood pressure. The Joint Commission on Accreditation of Healthcare Standards (JCAHO) has implemented new standards making pain management a required part of all treatment plans at accredited facilities. Accreditation by JCAHO is essential for reimbursement under Medicare, Medicaid, and most third-party health insurance plans. In addition, the National Committee for Quality Assurance is adding pain to its evaluation methodologies.

Unfortunately, just when the medical community has been awakening to the importance of pain management, a new thief has emerged to threaten patients'

hard-fought rights to adequate pain relief — robbing them and their families once again of the ability to lead normal lives. Some people have always abused opioid analgesics, both legal (prescription medications) and illicit (such as heroin). Now they have discovered OxyContin® (controlled-release oxycodone HCl) Tablets, and they are abusing it to produce a "high." The criminal activities of a minority of drug abusers, fanned by a spate of sensational reports in the media, have created tension between patients, their healthcare providers, and law enforcement. Unless balance is brought to this debate, a large majority of patients who suffer with pain are at risk of losing the effective treatment they desperately need.

The American Medical Association[2] and the American Society of Anesthesiologists[3] have endorsed the use of opioids as an appropriate option in treating chronic (persistent) pain. The U.S. Department of Health and Human Services' clinical practice guidelines for treating both acute pain and cancer pain recognize opioids as an essential part of a pain management plan. The American Bar Association has issued a strong and important statement of support for the pain movement:

"Resolved, that the American Bar Association urges federal, state, and territorial governments to construe, apply, and if necessary, amend laws regulating the health professions, controlled substances, insurance, and both public and private health benefit programs so that these laws do not impose barriers to quality pain and symptom management.

"Further resolved, that the American Bar Association urges federal, state, and territorial governments to support fully the right of individuals suffering from pain to be informed of, choose, and receive effective pain and symptom evaluation, management, and ongoing monitoring as part of basic medical care."[4]

Purdue is extremely concerned about the recent increase in abuse of diverted OxyContin Tablets. We stand side by side with law enforcement authorities in their efforts to bring to justice those who violate the nation's drug laws. The company has taken the initiative to work closely with the healthcare community and government agencies to devise measures to reduce the instances of abuse and diversion. Yet we are even more concerned about the larger human tragedy of pain — and are firmly committed to keeping pain-relieving medicines available for the millions of legitimate patients who need them most. We will not let these patients, and their families, suffer in silence. We are committed to being true "partners against pain®."

The serious public health problem of prescription drug abuse, and a number of the measures that Purdue has undertaken to deal with it, are presented in this report.

1. **What is the nature of the problem?** OxyContin® is an opioid analgesic used to treat moderate to severe pain. The approved FDA indication for this medication is "the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time." The medication has been sold in the United States since 1996. Each OxyContin Tablet delivers to the patient, over a period of 12 hours, a controlled release of a drug known as oxycodone. Like morphine, OxyContin is a Class II medication with recognized abuse potential. Like all Class II medications, it can only be obtained by written prescription from a physician who is licensed by the Drug Enforcement Administration. A new prescription must be written each time. From the time it was approved, the package insert and all promotional material for OxyContin cautioned:

"TABLETS ARE TO BE SWALLOWED WHOLE, AND ARE NOT TO BE BROKEN, CHEWED OR CRUSHED. TAKING BROKEN, CHEWED OR CRUSHED OxyContin TABLETS COULD LEAD TO THE RAPID RELEASE AND ABSORPTION OF A POTENTIALLY TOXIC DOSE OF OXYCODONE."

In July 2001, Purdue made changes to the physician prescribing information and package insert for OxyContin as part of its efforts to help reduce abuse and diversion of the medication — and sent letters to more than 800,000 healthcare professionals outlining these revisions (see attachment). The revised package insert (also attached) now begins with a boxed warning that calls attention to the product's potential for misuse, abuse, and diversion. The warning, which includes information drawn from parts of the original package insert, reads as follows:

WARNING:

OxyContin® is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine.

Oxycodone can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing OxyContin in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

OxyContin Tablets are a controlled-release oral formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

OxyContin Tablets are NOT intended for use as a prn analgesic.

OxyContin 80 mg and 160 mg Tablets ARE FOR USE IN OPIOID TOLERANT PATIENTS ONLY. These tablet strengths may cause fatal respiratory depression when administered to patients not previously exposed to opioids.

OxyContin® (oxycodone hydrochloride controlled-release) TABLETS ARE TO BE SWALLOWED WHOLE AND ARE NOT TO BE BROKEN, CHEWED, OR CRUSHED. TAKING BROKEN, CHEWED, OR CRUSHED OxyContin® TABLETS LEADS TO RAPID RELEASE AND ABSORPTION OF A POTENTIALLY FATAL DOSE OF OXYCODONE.

Within the past year and a half, there have been increasing reports of OxyContin Tablets being diverted and abused by drug abusers and addicts. Even so, all national data show that OxyContin abuse is a small fraction of the overall abuse problem. The pattern of OxyContin abuse usually involves crushing the tablets to obtain the full dose of oxycodone immediately and ingesting, snorting, or injecting it. In a number of cases, the media have reported overdoses and even deaths. At present, we believe that almost all of these reports involve people who are abusing the medication, some in combination with other substances, including alcohol — not patients under the treatment of a healthcare professional.

2. **Has the press coverage of OxyContin abuse had an effect on patients?** Unfortunately, the answer to this question is an unqualified yes. We have heard numerous reports that as a direct result of the fear and concern created by exaggerated media coverage of this problem, patients whose pain has been well controlled by OxyContin have asked their doctors to put them on other medications that may or may not be as successful. Some doctors have told us that they are switching patients to medications they regard as less effective because the media has made OxyContin controversial. There are many reports of pharmacies that will no longer carry the medication for their patients, and this is even more pronounced in pharmacies serving predominantly non-white patients. This has caused great injury to patients who suffer from chronic pain. Purdue has received hundreds of heart-rending letters from patients who are terrified that it will become more difficult for them to obtain relief from their pain. Here are just a few examples of their concerns:

   - "I am petrified that I might not be able to find a doctor to continue my treatment, especially with all the negative press surrounding this drug. I work 50 to 60 hours a week and without proper pain control I

don't know if I would be able to continue holding a job."

- "I am so passionate about getting the word out to the public about the benefits of pain management for patients, like myself, who rely on medications to manage on a day-to-day basis. We are not 'drug addicts' and we do not 'abuse' our medications. Yet on an ever-increasing basis, we are finding it harder and harder to get the medications we have come to rely on to cope with the intractable, debilitating pain we face each and every day."

- "I've been suffering with chronic pain for a few years now, and it's only getting worse. OxyContin DID help me, but because of all the press and publicity, my doctor's office no longer offers the medication to his patients."

- "I hope that all the bad press about the abuse of OxyContin on the streets doesn't affect the supply to those of us that need it in order to breathe and not scream in pain with every little move."

3. **What is the source of diverted OxyContin?** According to law enforcement experts, OxyContin and other legitimate prescription medications find their way into illicit channels by means of prescription fraud, "doctor shopping," or other methods of receiving inappropriate prescriptions from a doctor, theft, diversion from Mexico and Canada, and Internet pharmacies.

4. **How widespread is the problem?** Both Purdue and law enforcement are trying to understand the extent of this problem, since there are no reliable data available. It is our belief that the abuse of OxyContin Tablets is most evident in a few states, generally along the spine of Appalachia. We believe that in many cases, the media has misinterpreted the data and sensationalized the problem — particularly by attributing many deaths to OxyContin abuse that actually were caused by the abuse of multiple drugs, often including alcohol. We have engaged third parties to evaluate the death data provided by coroners and state medical examiners in order to more accurately determine how many deaths can correctly be attributed to OxyContin abuse. However, by examining these data ourselves, we have found numerous inaccuracies such as the following examples:

- In Kentucky, the media has reported — a story repeated dozens of times — that OxyContin caused the deaths of 59 people. Our contacts with the State Medical Examiner and local coroners established that a number of deaths resulted from combinations of illegal and legal drugs, which occasionally included oxycodone, the active ingredient in OxyContin. However, some 40 other medications also contain this ingredient, and OxyContin accounts for only 25 percent of the prescriptions for this type of medication. Thus far, reviews of the available autopsy reports have indicated that not a **single** death was attributable to OxyContin alone.

- In Maine, the media reported 35 deaths from OxyContin use. Our inquiries showed that there were two deaths in which OxyContin was the single cause of death, and one of those was a suicide.

- The media indicated that Blair County, Pennsylvania was an area of high OxyContin abuse, and we acknowledge this to be the case. However, the County Coroner reported to us that there were 58 deaths in the county from January 1996 through December 2000 — and that **none** of them was attributed to oxycodone alone. In fact, oxycodone (not necessarily OxyContin) was one of several medications found in only seven of those cases.

These statistics are provided not to minimize the tragedy of even a single loss of life, or of drug abuse and addiction, but as examples of how the press has made it so difficult to obtain an understanding of what is actually occurring. According to the most recently available annual data (2000) published by the U.S. Government's Drug Abuse Warning Network (DAWN), oxycodone in all forms was mentioned in 2% of all prescription medication-related Emergency Room visits in which abuse was suspected, ranking 14th on the list of drugs of abuse — well behind such well-known medications as diazepam, hydrocodone, acetaminophen, ibuprofen, and even aspirin.

5. **Could Purdue have foreseen the problem?** In more than 15 years of marketing other oral opioid analgesics, Purdue had no similar experience of abuse or diversion. Purdue had no reason to expect otherwise with OxyContin.

6. **What is Purdue doing about this situation?** Law enforcement officials have lauded Purdue's initiatives to help reduce the abuse of prescription medications. The Attorney General of Virginia said that as soon as Purdue learned of the problem, "it jumped in with both feet" to solve it. The Attorney General of Maryland praised Purdue's efforts and proposals. Several United States Attorneys have complimented Purdue for its cooperation and have requested that Purdue bring its anti-abuse and diversion programs to their region. In several cases the United States Attorney or his assistant has actually appeared on the Purdue program. Purdue's efforts to help resolve the problem have included the following:

   - Purdue has held fact-finding and briefing meetings with law enforcement and regulatory officials, including U.S. Attorneys, Attorneys General, the Drug Enforcement Administration, and the U.S. Food and Drug Administration.

   - There is a paucity of reliable data on the nature and extent of the problem of prescription drug abuse. Purdue has been working with government and independently to develop hard data. We are developing a predictive model that will help us identify areas where abuse of prescription medications might spread. Based on this analysis, we will intensify our education and prevention efforts in those regions of the country.

   - Purdue has communicated extensively on this subject with healthcare professionals. Abuse and diversion brochures have been mailed to nearly 500,000 doctors and more than 60,000 pharmacists. These brochures have been praised by law enforcement and welcomed by healthcare providers.

   - We have distributed "opioid documentation kits" to assist physicians in distinguishing between legitimate patients in pain and those feigning their pain to obtain narcotic medications.

   - Purdue has brought continuing education and other programs of the highest quality to the areas of abuse and diversion. These are nonpromotional programs, which teach doctors how to avoid being "scammed" by abusers and criminal diverters, how to properly assess and treat patients with real pain, and how to prevent diversion. Law enforcement officials have found these programs so valuable that

they have requested Purdue to bring additional programs to areas of greatest abuse and diversion.

- In selected regions experiencing the highest reported incidence of prescription medication abuse, Purdue has provided, at no cost to physicians, tamper-resistant prescription pads utilizing special technologies that make alteration extremely difficult.

- Purdue has made a substantial grant to work with the Virginia Attorney General to study Prescription Monitoring Programs ("PMPs"). These programs have proven successful in a number of states in defeating "doctor shopping." In other states they have been less successful. The objective of this study is to determine the elements of an ideal PMP, which would be supported by the medical community and law enforcement and would not interfere with the ability of a legitimate patient to receive appropriate prescription medications.

- Purdue is taking strong and effective measures to prevent criminal diversion of its products from Mexico and Canada. Tablets sold in those countries will have unique markings to enable law enforcement to identify where the product was dispensed. We believe that this step is unprecedented in the pharmaceutical industry.

- Purdue has been working quietly and without publicity with communities most affected by the problem and has put substantial resources toward helping them address their most immediate needs.

- Purdue is spending millions of dollars to research and develop new forms of strong pain relievers that would be resistant to abuse while at the same time providing safe and effective pain relief to legitimate patients. We hope to work with the FDA to accelerate the availability of these medications.

7. **Has Purdue been "overly aggressive" in marketing OxyContin® Tablets?** Purdue's marketing efforts for OxyContin have been conservative. We do no direct-to-consumer promotion, run very few journal advertisements, and provide doctors with no samples. Purdue is scrupulous in training its field sales force to promote OxyContin **only** for its approved indication. In the original package insert, the indication was "for the

management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days." In the package insert revised by Purdue in July 2001, the indication was rephrased to read "for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time." We monitor our field force for compliance with these policies. Sales representatives are told that in the event we learn of a violation of our marketing policies, the offender will be subject to discipline, up to and including termination. To further ensure that our representatives comply with the policies we have set, we are hand-delivering a letter to every healthcare provider on whom we call, setting forth our promotional standards and providing a toll-free telephone number to report any violations of those standards.

8. **Are there any risks associated with OxyContin if taken under a doctor's supervision?** As both the original and the new package inserts point out, "OxyContin® is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine." Another serious risk associated with opioids, including OxyContin, is respiratory depression. Common opioid side effects are constipation, nausea, sedation, dizziness, vomiting, pruritus, headache, dry mouth, sweating, and weakness. OxyContin is contraindicated in patients with known hypersensitivity to oxycodone, or in any situations where opioids are contraindicated. (Please see "Warnings" and "Contraindications" in the attached full prescribing information.)

9. **Is restricting the use of OxyContin the solution?** Some have suggested that restricting availability of OxyContin will help alleviate the problem. We are convinced that this is not so. Those intimately involved with the problem agree. Local law enforcement officers have told us that in most of the reported cases of overdose and death, OxyContin was neither the first nor the sole drug abused. We agree with the comments of knowledgeable law enforcement officers who have said that if OxyContin were not available, those abusing and addicted to drugs would not stop this behavior but would simply continue their abuse with other legal and illegal drugs.

10. **Would restricting the distribution of OxyContin help?** Some have suggested that Purdue limit the distribution of OxyContin to certain selected "central" pharmacies. We believe that this approach would not help the situation and might in fact create more problems. Central pharmacies are unlikely to have a material effect on the primary sources of OxyContin diversion. Limiting distribution would not prevent corrupt or uninformed doctors from writing inappropriate prescriptions. It would do little to prevent prescription alteration, and would have little effect on "doctor

shopping." It would not prevent patients from selling a portion of their medication. It would not prevent family members from stealing and re-selling a patient's medication. While central pharmacies might reduce the number of pharmacy robberies, that benefit is counterbalanced by the risk of robbery for central pharmacies known to hold large inventories of OxyContin. In addition, central pharmacies would deliver the medication to patients by mail or common carrier — and this would increase the risk of mailbox theft and other forms of in-transit theft. Beyond all this, distribution through central pharmacies would significantly increase the burden on patients who have a legitimate need for these medications. A patient in pain should not have to wait for delivery by mail or common carrier to obtain needed relief.

11. **What is the solution?** Minimizing the problem of drug abuse requires the cooperation of many elements in our community: the medical community, law enforcement, schools, religious institutions, parents and family, the courts, the press, federal and state legislators, social services providers, and the pharmaceutical industry. Purdue is taking the lead within our industry in addressing this critical social problem because we believe it is the right thing to do. What is needed is cooperation and common purpose, not divisive efforts to demonize a medication, a company, or an industry. This is a long-standing societal problem that requires a reasoned solution.

[1] The Fifth Vital Sign is a trademark of the American Pain Society.
[2] Report 4, Council on Scientific Affairs, Aspects of Pain Management in Adults, American Medical Association, June 1995.
[3] Practice Guidelines for Cancer Pain Management: A Report by the American Society of Anesthesiologists Task Force on Pain Management, Cancer Pain Section, 1996.
[4] American Bar Association, Commission on Legal Problems of the Elderly, Report to the House of Delegates, July 2000.

Attachments:

OxyContin® (oxycodone HCl) Tablets full prescribing information

Purdue's July 18, 2001 letter to healthcare professionals

Package Insert

1. PACKAGE INSERT

OXYCONTIN®

(Oxycodone HCl Controlled-Release) Tablets
10 mg 20 mg 40 mg 80 mg* 160 mg*

*** 80 mg and 160 mg for use in opioid-tolerant patients only**

OT00367

065570-0F-001

WARNING:

OxyContin is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine.

Oxycodone can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing OxyContin in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

OxyContin Tablets are a controlled-release oral formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

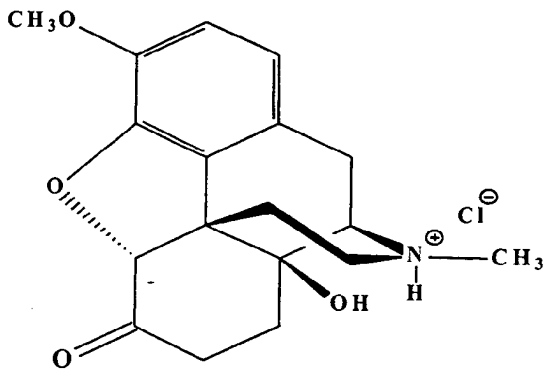
OxyContin Tablets are NOT intended for use as a prn analgesic.

OxyContin 80 mg and 160 mg Tablets ARE FOR USE IN OPIOID-TOLERANT PATIENTS ONLY. These tablet strengths may cause fatal respiratory depression when administered to patients not previously exposed to opioids.

OxyContin TABLETS ARE TO BE SWALLOWED WHOLE AND ARE NOT TO BE BROKEN, CHEWED, OR CRUSHED. TAKING BROKEN, CHEWED, OR CRUSHED OxyContin TABLETS LEADS TO RAPID RELEASE AND ABSORPTION OF A POTENTIALLY FATAL DOSE OF OXYCODONE.

DESCRIPTION

OxyContin® (oxycodone hydrochloride controlled-release) Tablets are an opioid analgesic supplied in 10 mg, 20 mg, 40 mg, 80 mg, and 160 mg tablet strengths for oral administration. The tablet strengths describe the amount of oxycodone per tablet as the hydrochloride salt. The structural formula for oxycodone hydrochloride is as follows:



$C_{18}H_{21}NO_4 \bullet HCl$ MW 351.83

The chemical formula is 4, 5-epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one hydrochloride.

Oxycodone is a white, odorless crystalline powder derived from the opium alkaloid, thebaine. Oxycodone hydrochloride dissolves in water (1 g in 6 to 7 mL). It is slightly soluble in alcohol (octanol water partition coefficient 0.7). The tablets contain the following inactive ingredients: ammonio methacrylate copolymer, hydroxypropyl methylcellulose, lactose, magnesium stearate, povidone, red iron oxide (20 mg strength tablet only), stearyl alcohol, talc, titanium dioxide, triacetin, yellow iron oxide (40 mg strength tablet only), yellow iron oxide with FD&C blue No. 2 (80 mg strength tablet only), FD&C blue No. 2 (160 mg strength tablet only) and other ingredients.

CLINICAL PHARMACOLOGY

Oxycodone is a pure agonist opioid whose principal therapeutic action is analgesia. Other members of the class known as opioid agonists include substances such as morphine, hydromorphone, fentanyl, codeine, and hydrocodone. Pharmacological effects of opioid agonists include anxiolysis, euphoria, feelings of relaxation, respiratory depression, constipation, miosis, and cough suppression, as well as analgesia. Like all pure opioid agonist analgesics, with increasing doses there is increasing analgesia, unlike with mixed agonist/antagonists or non-opioid analgesics, where there is a limit to the analgesic effect with increasing doses. With pure opioid agonist analgesics, there is no defined maximum